DEC 2 0 2001

K013340

510(k) Summary of Safety and Effectiveness

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[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:	PLUS ORTHOPEDICS 6055 Lusk Blvd. San Diego, CA 92121 Tel: 858-550-3800 x 2506 Attn: Mr. Hartmut Loch, RAC Director, Regulatory Affairs
Trade name:	RT-PLUS™ Knee System
Common name:	Hinged Knee Prosthesis
Classification name:	Prosthesis Knee, Femorotibial, Constrained, Cemented, Metal/Polymer § 888.3510 - Class II Product Code: KRO - 87 Orthopedic Device Panel
Predicate Device:	RT-PLUS Knee System, S/E May 11, 2001 - K003504 manufactured by PLUS Endoprothetik AG, Switzerland
Device Modification Description:	The RT-PLUS™ Additional Knee Components are identical to the predicate device, except sizes 2 and 10 were added to the existing sizes 4, 6, and 8 of the RT-PLUS™ Knee System.
Indications:	The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.
Contraindications:	Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.
Performance data:	Biomechanical fatigue tests have been performed on the worst-case model. The test results of the additional components were favorable to the predicate device and are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, CA 92121-2700

DEC 2 0 2001

Re: K013340
Trade/Device Name: RT-PLUS" Hinged Knee
Regulation Number: 21 CFR §888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: November 16, 2001
Received: November 20, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(K) DEVICE MODIFICATION
RT-PLUS Knee Additional Components
October 5, 2001

510(k) Number: K013340

Device Name(s):

RT-PLUS Knee Additional Components

Indications for Use:

The RT-PLUS™ Knee System is a tri-compartmental rotating hinged prosthesis of the total condylar type. The system consists of femoral, tibial and patellar components. It is indicated for use as a replacement of the knee joint in which significant bone loss and/or ligamentous deficiencies have occurred due to tumors, trauma, infection, revision or connective tissue disorders. The RT-PLUS™ Modular Cemented Knee provides joint stability when any or all of the following structures are non-functional: MCL, LCL, PCL, ACL and the iliotibial band.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013340

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)